REMARKS

Claims 1-3 and 5-23 are pending in the present Application. Claims 21-23 were withdrawn from consideration. No claims have been canceled, amended, or added, leaving Claims 1-3 and 5-20 for consideration upon entry of the present Amendment.

Reconsideration and allowance of the claims are respectfully requested in view of the following remarks.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1-3 and 5-18 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent No.6,183,248, Chishti et al. in view of Conn et al (2002/0082360). Applicants respectfully traverse this rejection.

Examiner has stated that "[i]t is believed that the claimed stain resistance of the shell is inherently present in the polymeric shell comprising the claimed polymeric mixture even though it is not explicitly recited in the prior art" and that "[i]t is believed that the shell polymeric mixture of the prior art is stain resistant." (Office Action dated January 11, 2006). Applicants first submit that these statements fail to make clear what exactly is the basis for the Examiner's rejection. For example, the first statement appears to repeat Applicants' Claim 1. The Examiner compounds this confusion by failing to make clear which prior art polymeric mixture is being referred to in the second statement.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a prima facte case of obviousness, i.e., that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Fine, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); In Re Wilson, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); Amgen v. Chugai

Pharmaceuticals Co., 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The claimed invention is directed to an appliance for use in an oral cavity, wherein the appliance comprises a stain resistant polymeric shell that has cavities designed to receive teeth, and wherein the shell comprises a thermoplastic polymeric mixture that comprises a polycarbonate and a cycloaliphatic polyester.

Chishti teaches a polymeric overlay or shell having a teeth-receiving cavity formed therein. (see Abstract) Chishti teaches that the shell comprises at least one layer of polymeric material. (see Claim 1) Chishti discloses that the layer of polymeric material can be a shape memory polymer, methacrylate containing polymers, acrylate containing polymers, thermoplastic polymers, cross-linked thermoplastic polymers, thermoplastic polymer blends, cross-linked thermoplastic polymer blends, thermoplastic elastomer polymers, and thermoset polymers. (see Claim 6) Chishti further teaches that a layer of the shell can comprise a crosslinked polyester/polycarbonate blend in the Table in Col. 10. (see heading to the Table in Col. 10)

Conn teaches films formed from a blend of polycarbonate and a copolyester. (see Abstract) Conn teaches that the copolyester component of the blend at least one, or more of poly(1,4-cyclohexylene- dimethylene terephthalate) (PCT), poly(1,4-cyclohexylenedimethylene naphthalenedicarboxylate) (PCN), poly(1,4-cyclohexylenedimethylene 1,4-cyclohexanedicarboxylate) (PCC) copolyesters, or mixtures thereof. (see Page 1, paragraph [0011]) However, the blends of polycarbonate and copolyester disclosed by Conn undergo yellowing. (see page 3, paragraph [0029]) Conn also teaches that in order to prevent yellowing, a phosphite stabilizer must be added to the blend. (see page 3, paragraph [0029])

Applicants respectfully submit that the Examiner has failed to provide a motivation to combine the references or that there would be a reasonable expectation of success if the references were combined. The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. See MPEP § 706.02(j). "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to

have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

The Examiner appears to have misunderstood Applicants' earlier arguments regarding the lack of motivation to combine the teachings of Chishti and Conn. One of ordinary skill in the art would not be motivated to combine the teachings for at least three reasons.

- (1) Conn teaches that its blends undergo a yellow discoloration. Upon reading Conn, one of ordinary skill in the art would not be motivated to combine the blends of Conn that undergo a yellow discoloration with Chishti to make a dental appliance system for stabilizing teeth because the yellow discoloration would reduce the aesthetic appeal of the appliance. In fact, Applicants submit that one of ordinary skill in the art would understand Conn to expressly teach against the use of its blends for dental appliances that require an aesthetic appeal.
- (2) Conn teaches that the yellow discoloration can be suppressed by the addition of a phosphite stabilizer. Upon reading Conn, one of ordinary skill in the art would understand that in order to use the polymer blends of Conn in an aesthetically appealing dental appliance system, a phosphite stabilizer must be added. One of ordinary skill in the art, however, would not seek to add a phosphite stabilizer to a resin that is being placed in the mouth without proper medical testing and FDA approval.
- (3) Chishti teaches that crosslinked polycarbonate polycster blends are used in a dental appliance system. (see Abstract) Conn teaches that the polycarbonate-cycloaliphatic polyester blends are thermoplastics. Evidence of this can be seen from the fact that the blends are thermoformable. (see Examples; see also paragraph [0043] on page 4) Therefore, one of ordinary skill in the art upon reading Chishti and noting the use of crosslinked (i.e., thermosetting) resins would not seek to combine it with Conn's thermoplastic resins.

For these reasons at least, the artisan skilled in the art would not be motivated to combine Chishti with Conn in the manner undertaken by the Examiner. In addition, the references do not expressly or impliedly suggest a reasonable expectation that the proposed combination would successfully provide a suitable dental appliance system.

Even if Chishti and Conn were combined, the combined teachings fail to disclose all elements of the claimed invention. While Chishti teaches that the shell can comprise thermoplastic polymer blends and thermoset polymers including a crosslinked

polyester/polycarbonate blend, Chishti does not teach a shell that comprises a thermoplastic polymeric mixture that comprises a polycarbonate and a cycloaliphatic polyester as presently claimed. Further, Chishti does not teach a polycarbonate-cycloaliphatic polyester blend that is stain resistant. For this reason at least, Chishti does not teach all elements of the claimed invention. Conn also fails to disclose a stain resistant polycarbonate-cycloaliphatic polyester blend and therefore cannot remedy the deficiency of Chishti.

It is respectfully submitted that the Examiner has inappropriately used the doctrine of inherency in putting forth a rejection under 35 U.S.C. §103 (a). The courts have made the distinction that "the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." In re Sportmann, 150 U.S.P.Q. 449, 452, (CCPA, 1966). Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. In re Rijckaert, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993); MPEP § 2141.02(V). Consequently, the Federal Circuit has held that the theory of inherency is normally reserved for rejections under 35 U.S.C. § 102. In re Grasseli, 218 U.S.P.Q. 769, 772 (Fed. Cir. 1983). Withdrawal of the rejection of obviousness under inherency is respectfully requested.

Even if an obviousness rejection can be based solely on a theory of inherency, the Examiner's statement that "[i]t is believed that the shell polymeric mixture of the prior art is stain resistant," without more, is an insufficient basis upon which to assert a theory of inherency. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). In Levy, the Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency. See MPEP § 2112 (IV). Applicants respectfully submit that the Examiner has failed to provide the necessary basis required to rely on a theory of inherency and therefore the Examiner has failed to meet his burden of a prima facie showing of obviousness.

Even where a prima facte case of obviousness exists, obviousness may be rebutted by a showing of "unexpected results," i.e., comparative test data showing that the claimed invention possesses unexpectedly improved properties, or properties that the prior art does not have. In re Dillon, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990) (emphasis added). The results must be of both statistical and practical significance. Exparte C, 27 U.S.P.Q.2d 1492, 1497 (Bd. Pat. App. & Int. 1993).

The Examiner has stated that "the applicant presents argument pertaining to the natural coloration of the polymer, which is not claimed." Applicants' arguments were directed to the lack of yellow discoloration of the claimed invention, which is claimed, contrary to Examiner's assertion. (Claim 13). More substantively, however, there is no requirement that the unexpected properties be claimed to rebut a *prima facie* case of obviousness. Instead, the unexpected properties are indicia that the claimed invention is nonobvious over the prior art.

The claimed invention possesses at least two unexpected properties that the prior art does not have: (1) stain resistance as shown in Table 6 and paragraph [0095] and Table 14 and paragraph [0112]; and (2) lack of yellow discoloration as shown in Table 12 and described in paragraphs [0106] and [0107]. These unexpected properties demonstrate that the claimed invention is indeed distinguishable from the prior art polymeric mixtures and therefore can rebut a prima facte case of obviousness. In addition, the unexpected properties are claimed in Claim 1 and Claim 13, respectively. For at least the foregoing reasons, Chishti and Conn fail to disclose a stain resistant polymeric shell comprising a thermoplastic polymeric mixture that comprises a polycarbonate and a cycloaliphatic polyester, as required by Claim 1. Therefore, Chishti and Conn cannot render obvious Claim 1 and its dependent claims. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 19 and 20 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent No.5,975,893, Chishti et al. in view of Chishti et al. 6,183,248 and Conn. Applicants respectfully traverse this rejection.

Claim 19 is directed to a method for maintaining or repositioning teeth in the oral cavity comprising: placing an appliance in a patient's mouth, wherein the appliance comprises a stain resistant polymeric shell having cavities designed to receive teeth, and wherein the appliance comprises a polymeric mixture, that comprises a polycarbonate and a cycloaliphatic polyester.

As described above, Chishti '248 and Conn fail to disclose a stain resistant polymeric shell that comprises a thermoplastic polymeric mixture that comprises a polycarbonate and a cycloaliphatic polyester. Chishti '893 fails to disclose a polymeric mixture and cannot remedy the deficiency of Chishti '248 and Conn. Therefore the combined teachings of Chishti '893, Chishti '248, and Conn cannot render obvious Claims 19 and 20. Reconsideration and withdrawal of this rejection are respectfully requested.

It is believed that the foregoing remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and withdrawal of the rejections and allowance of the case are respectfully requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 50-3621.

Respectfully submitted,

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